DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 28 2009

Food and Drug Administration
Rockville MD 20857

Re: Lexiscan
Patent Nos. 6,403,567 and 6,642,210
Docket Nos.: FDA-2009-E-0048
FDA-2009-E-0047

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,403,567 and 6,642,210, filed by CV Therapeutics, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lexiscan (regadenoson monohydrate), the human drug product claimed by the patents.

The total length of the regulatory review period for Lexiscan (regadenoson monohydrate) is 2,446 days. Of this time, 2,113 days occurred during the testing phase and 333 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 1, 2001.

   The applicant claims August 2, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 2001, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: May 14, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA) 22-161 was submitted on May 14, 2007.

3. The date the application was approved: April 10, 2008.

   FDA has verified the applicant's claim that NDA 22-161 was approved on April 10, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Daniel W. Collins
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